

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMACEUTICALS INC. and)	
SANOFI-AVENTIS US LLC,)	
)	
Plaintiffs,)	
)	C.A. No. 06-286 (GMS)
v.)	
)	
BARR LABORATORIES, INC.)	REDACTED – PUBLIC VERSION
)	
Defendant.)	
)	

**REPLY BRIEF IN SUPPORT OF BARR LABORATORIES' RULE 12(b)(6)
MOTION TO DISMISS PLAINTIFFS' WILLFUL INFRINGEMENT CLAIMS
OR, ALTERNATIVELY, TO BIFURCATE AND STAY DISCOVERY ON THEM**

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I. INTRODUCTION.

Plaintiffs' willful infringement claims fail as a matter of law. The Federal Circuit does not permit them. See *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004). And the majority of courts to confront this issue agree. Plaintiffs attempt to prop up their infirm willfulness claims by relying on Barr's subsequently-filed counterclaims. The fact is, Plaintiffs' infringement claims are, and must be, based entirely on the artificial act of infringement set forth in 35 U.S.C. § 271(e)(2). Plaintiffs may not "hang[] a finding of willfulness on such a special-purpose peg" as § 271(e)(2). *Glaxo*, 376 F.3d at 1351. The claims should be dismissed.

If they are not dismissed, they should be bifurcated. Plaintiffs are wrong when they assert that Barr will not suffer a *Quantum* dilemma if Plaintiffs are allowed to proceed at this juncture with their willfulness claims. Barr will either have to waive privilege or forego a viable and perhaps even essential defense to Plaintiffs' willfulness claims. Moreover, Plaintiffs' complaints about inefficiencies that might result from bifurcation do not withstand scrutiny. They cite to only one area of overlap between liability and willfulness – copying – which in this case will be no more than a tiny part, if any part at all, of either proceeding. Bifurcation is warranted if the claims are not dismissed.

II. ARGUMENT.

A. Plaintiffs Do Not And Cannot State A Claim For Willful Infringement.

Plaintiffs' complaint does not and cannot state a claim for willful infringement under *Glaxo*. Accordingly, their willful infringement claims should be dismissed.¹

¹ Plaintiffs complain that Barr incorrectly styled its motion as a Rule 12(b)(6) motion. (See Pls' Br. at 3 n.1). Barr, however, set forth its defense of failure to state a claim in its answer. (See D.I. 6 at 6). This was sufficient to preserve the motion. See Fed. R. Civ. P. 12(h)(2) (permitting defense of failure to state a claim to be set forth in pleading); *Gerakaris v. Champagne*, 913 F. Supp. 646, 650-51 (D. Mass. 1996) (holding that defendants preserved motion to dismiss for failure to state a claim filed after the answer by raising it as affirmative defense in answer); *Doolittle v. Ruffo*, 882 F. Supp. 1247, 1257 n.9 (N.D.N.Y. 1994) (considering 12(b)(6) motion to dismiss filed after answer where defense was pled in answer). Even if Barr's motion was untimely filed, Barr respectfully requests that

1. Barr's Counterclaims Do Not Provide Support For Plaintiffs' Willful Infringement Claims.

Plaintiffs concede that, if Barr engaged in no allegedly infringing conduct other than its ANDA filing, "Barr might have a colorable argument that [Plaintiffs] could not sustain a willful infringement claim." (Pls' Br. at 1). After conceding this point, Plaintiffs rely on *Barr's* responsive pleading to suggest that there is some infringing conduct outside of Barr's ANDA filing. (*Id.* at 6-8). According to Plaintiffs, because Barr's counterclaims seek declarations of non-infringement, "Barr's Answer may seek to bring into play more than just § 271(e)(2) infringement." (*Id.* at 8). Plaintiffs' argument misapprehends the Hatch-Waxman statutory scheme.

As an initial matter, Plaintiffs brought their willful infringement claims *before* Barr filed its counterclaims. If Barr's subsequently-filed counterclaims provide the basis for Plaintiffs' willful infringement claims, it is not clear what basis Plaintiffs had to bring those claims in the first instance. Moreover, Plaintiffs' response brief, while cryptically referring to other acts of infringement, fails to identify a single concrete act beyond Barr's ANDA submission that could form the basis for Plaintiffs' willful infringement claims.

This simply demonstrates that Barr's counterclaims are irrelevant to Plaintiffs' willful infringement claims. Plaintiffs have no legal ground for their infringement claims other than § 271(e)(2). Through the Hatch-Waxman Act, Congress expressly provided that a generic drug maker's pre-launch activities in furtherance of its application for regulatory approval do not constitute patent infringement: "It shall not be an act of infringement to make, use, offer to sell,

the Court consider it as a Rule 12(c) motion for judgment on the pleadings, as it was filed only a week before the pleadings were closed. *See* Fed. R. Civ. P. 12(h)(2); *Turbe v. Gov't of V.I.*, 938 F.2d 427, 428 (3d Cir. 1991) (considering 12(b)(6) motion as 12(c) motion); *Hayes v. Invigorate Int'l Inc.*, No. Civ. A. 04-1577, 2004 WL 2203732, at *3 (E.D. Pa. Sept. 24, 2004) (holding that court should decide properly preserved 12(b)(6) motion to dismiss even if not in technical compliance with the rule) (Ex. 23).

or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs” 35 U.S.C. § 271(e)(1). This safe harbor prevents a branded drug maker, like Plaintiffs, from suing an ANDA applicant, like Barr, for infringement for any activities related to developing its generic product. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (observing that § 271(e)(1) “disable[s]” patent holder from establishing there has been an act of infringement).

There is one exception to the § 271(e)(1) safe harbor, and it is found in § 271(e)(2). Under § 271(e)(2), a patentee may sue an ANDA applicant when, and only when, the applicant submits the ANDA and the ANDA seeks approval before the expiration of the patent. *See* 35 U.S.C. § 271(e)(2)(A). Section 271(e)(2) is designed to “provide patentees with a defined act of infringement” that creates subject matter jurisdiction for a court to resolve patent infringement and validity issues. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997); *see also Eli Lilly*, 496 U.S. at 678 (“[A]n act of infringement had to be created for these ANDA and paper NDA proceedings. That is what is achieved by § 271(e)(2) . . .”).

Thus, notwithstanding Plaintiffs’ cryptic references to other acts of infringement that are purportedly lurking in Barr’s counterclaims, Plaintiffs have no ability or legal basis to sue Barr for infringement other than through the statutory mechanism set forth in § 271(e)(2). And the Federal Circuit has concluded that a district court may not “hang[] a finding of willfulness on such a special purpose peg” as § 271(e)(2). *Glaxo*, 376 F.3d at 1351.

Not surprisingly, Plaintiffs cite no authority for their theory that Barr’s counterclaims may provide the foundation for their willful infringement claims. There is none. Indeed, several of the cases in which courts dismissed such willful infringement claims involved

declaratory judgment counterclaims of noninfringement. (See Ex. 18 at 14-15; Ex. 19 at 6-7; Ex. 20 at 7; Ex. 21 at 6).² Notably, none of those courts even mention the counterclaims. See *In re '318 Patent Infringement Litig.*, C.A. No. 05-356 (KAJ), Hearing Tr. at *5-*7 (D. Del. Mar. 3, 2006) (Ex. 8); *Allergan, Inc. v. Alcon Inc.*, C.A. No. 04-968 (GMS), 2005 WL 3971927, at *2 (D. Del. July 26, 2005) (Ex. 2); *UCB Societe Anonyme v. Mylan Labs., Inc.*, No. 1:04-CV-683-WSD, 2006 WL 486895, at *2 (N.D. Ga. Feb. 28, 2006) (Ex. 16); *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, C.A. No. 3:04-1689 (MLC), Hearing Tr. at *8-*10 (D.N.J. Apr. 18, 2005) (Ex. 11).

Plaintiffs are grasping at straws. Barr's counterclaims could not have been the basis for Plaintiffs' willful infringement claims when they filed their complaint. And they do not provide a post hoc foundation for Plaintiffs' willful infringement claims, either. Plaintiffs' willful infringement claims can only be based on § 271(e)(2) for Barr's ANDA filing with paragraph IV certifications. *Glaxo* precludes those claims.

2. *Glaxo* Requires Dismissal Of Plaintiffs' Willful Infringement Claims.

Plaintiffs contend that their willful infringement claims may move forward to discovery despite *Glaxo*. (Pls' Br. at 8-10). But Plaintiffs completely ignore the underlying facts and the reasoning of *Glaxo*. *Glaxo* requires dismissal of those claims.

Plaintiffs ignore the fact that the patentee in *Glaxo* actually had evidence of willful infringement – evidence that the district court relied on to find willful infringement and that the Federal Circuit did not discredit. See *Glaxo Group Ltd. v. Apotex, Inc.*, 268 F. Supp. 2d 1013, 1033-35 (N.D. Ill. 2003) (finding that ANDA filer willfully infringed patent by failing to get opinion of counsel and admitting infringement in its own patent application); *Glaxo*, 376 F.3d at 1349-51. Yet, the Federal Circuit refused to affirm the willful infringement finding,

² "Ex. ___" refers to Exhibits 1-17 submitted with Barr's Opening Brief and Exhibits 18-23 submitted with this Reply Brief.

(emphasis added); *Aventis Pharma Deutschland GmbH v. Cobalt Pharms., Inc.*, 355 F. Supp. 2d 586, 592 (D. Mass. 2005) (“[T]his court cannot read the words ‘or certification’ in the *Glaxo* holding as mere surplusage.”); *Ortho-McNeil*, C.A. No. 3:04-1689 (MLC), Hearing Tr. at *9-*10 (same).

Given the willful infringement conduct in *Glaxo* and the Federal Circuit’s analysis of the underlying statutory scheme, the Federal Circuit’s decision can only be read as precluding willful infringement claims stemming from infringement claims arising under § 271(e)(2). The majority of district courts that have analyzed the *Glaxo* case since then, including this Court, have reached that conclusion and jettisoned willful infringement claims that are indistinguishable from Plaintiffs’. See *Allergan*, 2005 WL 3971927, at *2; Barr Opening Br. at 6-7 (listing cases). Moreover, nearly all courts have done so on the pleadings alone, without allowing additional discovery. See *Item Dev. AB v. Sicor Inc.*, No. Civ. 05-336-SLR, 2006 WL 891032, at *2 (D. Del. Mar. 31, 2006) (dismissing willful infringement claims against ANDA applicant) (Ex. 10); ‘318 Patent, C.A. No. 05-356 (KAJ), Hearing Tr. at *5-*7 (dismissing willful infringement claims against ANDA applicants based on *Glaxo* and *Allergan* decisions, among others); *UCB*, 2006 WL 486895, at *2 (dismissing willful infringement claims against ANDA applicants); *Celgene Corp. v. Teva Pharms. USA, Inc.*, 412 F. Supp. 2d 439, 445 (D.N.J. 2006) (same); *Lupin Ltd.*, 409 F. Supp. 2d at 730-31 (same); *Ortho-McNeil*, C.A. No. 3:04-1689 (MLC), Hearing Tr. at *8-*10 (same); *Cobalt Pharms.*, 355 F. Supp. 2d at 592-93 (same).³

³ It is unclear from this Court’s *Allergan* decision whether the Court struck the willful infringement allegations or dismissed them on the pleadings. It is also unclear, contrary to Plaintiffs’ assertions, whether any discovery was ever taken on the claims. What is clear, however, is that the Court held that willful infringement claims based on an allegedly baseless paper NDA filing cannot be sustained. See *Allergan*, 2005 WL 3971927, at *2. Thus, Plaintiffs’ attempted distinction with this case fails. Moreover, it is unclear in the *SmithKline* transcript whether the Court had the benefit of full briefing on the issue. *SmithKline & French Labs., Ltd. v. Teva Pharms., USA, Inc.*, C.A. No. 05-197-GMS, Hearing Tr. (D. Del. July 28, 2005) (Ex. 14). Since that decision, numerous courts analyzing *Glaxo* have dismissed willfulness claims. These decisions further clarify the issues surrounding the *Glaxo* decision and reasons

Finally, Plaintiffs' accusations that Barr's notice letter "provides a very flimsy rationale for invalidity" and is insufficiently specific are not only inadequate to sustain Plaintiffs' willfulness claims, but also incorrect.

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In sum, Plaintiffs cannot proceed with discovery on their willful infringement claims because they are based on § 271(e)(2)'s artificial act of infringement. They are therefore precluded under *Glaxo*. Plaintiffs' claims should be dismissed.

B. Alternatively, Plaintiffs' Willful Infringement Claims Should Be Bifurcated.

If the claims are not dismissed, they should be bifurcated and discovery on them stayed. Plaintiffs understate the prejudice to Barr if bifurcation is not granted and overstate the purported inefficiencies if bifurcation is granted.

Plaintiffs understate the prejudice to Barr by arguing that Barr does not face a *Quantum* dilemma because the Court is no longer permitted to draw an adverse inference if Barr

for concluding that willful infringement claims should be dismissed. *See, e.g., Celgene*, 412 F. Supp. 2d at 444-45 (analyzing *Glaxo* facts and reasoning in detail).

⁴ Contrary to Plaintiffs' suggestion, courts frequently invalidate patents based on prior art that was before the patent examiner. *See, e.g., IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1381, 1383 (Fed. Cir. 2005) (holding patent anticipated by prior art reference that was before the examiner and observing that "a patent may be found to be anticipated on the basis of a reference that had properly been before the patent examiner"); *Prima Tek II, L.L.C. v. Polypap, S.A.R.L.*, 412 F.3d 1284, 1287, 1290 (Fed. Cir. 2005) (holding patent anticipated by prior art before the examiner); *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1319-23 (Fed. Cir. 2004) (holding patent obvious in view of prior art before the examiner); *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1326-29 (Fed. Cir. 2004) (same).

does not produce an opinion of counsel. (See Pls' Br. at 11 (citing *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1341 (Fed. Cir. 2004))). This is wrong. The *Quantum* court did not rely on the adverse inference in discussing the dilemma. See *Quantum Corp. v. Tandon Corp.*, 940 F.2d 642, 643-44 (Fed. Cir. 1991). And the advice of counsel defense did not disappear with the *Knorr* decision. Barr would still be forced to choose between waiving privilege and foregoing an advice of counsel defense. If it foregoes the defense, Barr would face the risk of a willful infringement finding even without an adverse inference.

There is a reason companies continue to expend considerable time and resources to obtain patent opinions even after *Knorr-Bremse*. Simply because the risk might be lessened does not eliminate the prejudice Barr would face by having to choose between the lesser of two evils. Even in a case Plaintiffs rely on to argue against bifurcation, *Kos Pharmaceuticals, Inc. v. Barr Laboratories, Inc.*, 218 F.R.D. 387 (S.D.N.Y. 2003), the court recognized the prejudice ANDA applicants face and divided the trial into two phases, with discovery on legal opinions to take place only after the liability phase. *Id.* at 394.

In addition, Plaintiffs' complaints of overlap and inefficiencies are exaggerated. (See Pls' Br. at 12-14). Plaintiffs would not necessarily have to present evidence twice since the Court is statutorily required to decide whether to award attorney's fees under § 285, even if a jury hears the liability case. See 35 U.S.C. § 285 ("The court in exceptional cases may award reasonable attorney fees to the prevailing party.") (emphasis added). In any event, Plaintiffs identify only a single liability issue that overlaps with willfulness – copying. This issue will be minor or even entirely nonexistent because FDA generally requires ANDA applicants to use the same excipients in topical drug products like the one at issue here. See 21 C.F.R.

§ 314.94(a)(9)(v). Thus, evidence of copying is of little probative value in these ANDA cases. See *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, No. IP 99-38-C H/K, 2001 WL 1397304, at *14 (S.D. Ind. Oct. 29, 2001) (Ex. 22).

Because the prejudice to Barr is great, and the potential inefficiencies are minimal or nonexistent, Barr requests that this Court bifurcate and stay discovery on Plaintiffs' willful infringement claims, if they remain in the case.

III. CONCLUSION.

For the reasons set forth above and in Barr's Opening Brief, Barr respectfully requests that this Court dismiss Plaintiffs' willful infringement claims for failure to state a claim or, alternatively, to bifurcate and stay discovery on them.

Dated: June 28, 2006

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Karen E. Keller, Esquire, hereby certify that on July 5, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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